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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,276	12/06/2001	Roy L. Barrus	S-8492 (1502-71 CIP II)	4052
55825	7590	02/27/2006		
CARTER, DELUCA, FARRELL & SCHMIDT, LLP 445 BROAD HOLLOW ROAD SUITE 225 MELVILLE, NY 11704			EXAMINER WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/016,276

Applicant(s)

BARRUS ET AL.

Examiner

Catherine S. Williams

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 15-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14, 33 and 35-40 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/05 has been entered.

### ***Priority***

The petition to claim benefit under 35 U.S.C. 120 of a prior filed application (37 C.F.R. 1.78(a)(3) submitted 12/01/04 has been received, made part of the application file and forward to the office of petitions for review.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,9,11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuracina et al (US Pat# 5,879,337). Kuracina discloses a device including a needle (10) having a distal portion and a proximal portion. See figures 16+. The device also includes a shield (see figures 16 and 17) having at least one elongated part (19), a proximal end mounted with the proximal

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end of the needle, and a distal end mounted with a planar contact surface (22). See also figures 30 and 31. The planar contact surface (22) includes a needle linear bearing (47) that slidably engages (see 9:5-6; 13:11-12 and 19:54-55) the needle to facilitate movement of the needle relative to the shield. The shield is extensible between a retracted position and an extended position (see figures 16-17) via fixed positioning of the planar contact surface relative to movement of the shield. Regarding the claim limitation of “via fixed positioning of the planar contact surface relative to movement of the shield”, if one holds the distal portion of the needle shield (22) and releases the appendage (26) the force of the elongated part (19) will move the proximal portion of the shield relative to the planar contact surface (22).

Regarding claims 2-6 and 9, the device also includes a needle hub (112) that supports the proximal portion of the needle. See figures 5-7. The needle hub includes an appendage (26) with an opening (see figure 15 for the opening that is formed between the appendage 26 and the shield in the retracted position) and a wing (27). The shield includes at least one segment (19) that includes a channel (opening through segment/elongated part 19).

Regarding claim 11-13, the device also includes a latch (41) engageable with the needle where the latch includes an arm (see figures 30-31) for maintaining the shield in the extended position (see figure 31) and a plurality of surfaces (the distal end and side surface of the interior of the latch arm (41) configured to maintain the shield in the extended position (see figure 31).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuracina.

Kuracina meets the claim limitations as described above but fails to include the latch having an arcuate surface being engageable with the needle.

However, it would have been an obvious matter of design choice by one skilled in the art to make the inside surface of the needle latch either at a right angle as shown in figures 30-31 of Kuracina or having a curved corner as claimed. Applicant has not disclosed that the latch having an arcuate surface solves a particular problem, is used for a particular purpose or provides an advantage. Furthermore, one would expect Kuracina's latch and applicant's arcuate surface latch to perform equally well given that both would perform the function of retaining the needle within the shield given that, in the prior art, it is the inside distal surface of the latch that prevents the needle tip from being accessed after use. The prior art latch performance would not be affected with either a curved latch or a latch having a right angle. Therefore, the modification would have been considered a mere obvious design choice that fails to patentably distinguish over the prior art.

Claims 1,7, 33,36 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (USPN 6,824,530) in view of Kuracina. Wagner discloses a device including a ninety degree angle needle (16) having a distal portion and a proximal portion. See figures 3 and 14-17. The device also includes a shield (see figure 17) having at least one elongated part (46), a proximal end mounted with the proximal end of the needle, and a distal end mounted with

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a planar contact surface (56). See also figures 14-17. The shield is extensible between a retracted position (figure 14) and an extended position (figure 17) via fixed positioning of the planar contact surface relative to movement of the shield. Regarding the claim limitation of “via fixed positioning of the planar contact surface relative to movement of the shield”, see the disclosure of the operation of the needle 4:60-5:16. The device also includes a distal end of the foldable legs (46) of the shield being hingedly attached to the circular portion (56) of the planar contact shield (56).

Wagner meets the claim limitations as described above but fails to include the planar contact surface having a linear bearing that slidably engages the needle and a latch. However, Kuracina discloses such a linear bearing and latch.

At the time of the invention, it would have been obvious by one skilled in the art to modify the distal end interior of the needle shield (54) of Wagner (the embodiment of figure 14-17) by incorporating the linear needle bearing (47) and latch (41) as taught by Kuracina (figures 30-31). Both devices are analogous in the art of needle shields; therefore, a combination is proper. Additionally, as taught by Wagner, the linear bearing (47) in conjunction with the latch (41) work to automatically entrap or capture the sharpened tip of the needle after use (see 3:26-28). One skilled in the art would recognize the advantage of having a needle mechanism that “automatically” entraps the tip of the needle when the shield is actuated. Wagner fails to provide this type of entrapment and the motivation for the incorporation would have been to enhance the shielding of the needle by the Wagner shield with an entrapment mechanism. This incorporation would also enhance the safety to the medical technician during the use of the device.

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Claims 8, 35, 37 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner in view of Kuracina in further view of Bell (US Pat# 5,997,504). Wagner in view of Kuracina meet the claim limitations as described above but fail to teach the planar contact surface having a pad, an anchor part, and texturing.

Bell discloses a safety shield apparatus including needle (16,18) and a shield (see figures 12A-12C). The shield includes at least one elongated part with a proximal end mounted with the proximal portion of the needle and a distal end mounted with a planar contact surface (120). The planar contact surface also has a linear bearing (131) that slidably facilitates movement of the needle relative to the shield. See figure 11. The shield is shown being extensible between a retracted position and an extended position via relative movement between the surface (120) and the proximal portion of the shield (see figures 12A-12C). The device further includes a needle hub (104), an appendage wing (44), segment (28) and channel (inside 28). A latch (112) is shown in figure 12D with an arm having a plurality of surfaces including an arcuate surface. The needle is angularly displaced approximately 90 degrees (see figure 4A). **The planar contact surface includes an anchor/pad (122) which is an adhesive pad (texturing due to the adhesive).** The distal end of the shield is hingedly attached to the contact surface (see figures 12A and 12B).

At the time of the invention, it would have been obvious to incorporate the teaching of the pad/anchor of Bell on to the planar contact surface of Wagner in view of Kuracina. The devices are analogous in the art of needle shields and therefore a combination is proper. Additionally, the anchor/pad of Bell facilitates an efficient and comfortable securing of the device to the patient. See paragraph 37 of Bell. Additionally, one skilled in the art would

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recognize the advantage of having a comfortable and secure attachment mechanism to the patient. The disclosure of Wagner states that in the operation of the device one has to hold down the planar contact surface while pulling up the needle hub. See step 3 at 5:1-9. One skilled in the art would recognize that having an adhesive pad/anchor on the device of Wagner in view of Kuracina would eliminate the need for holding down the planar contact surface; thus, making the device of Wagner in view of Kuracina easier to use.

#### ***Allowable Subject Matter***

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

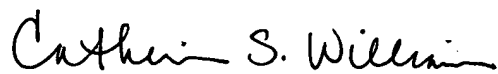
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Catherine S. Williams  
April 12, 2005